



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,502	01/28/2004	Maryse Lafouasse	P06312US01 - PHI 1367	3477

27142 7590 01/12/2006

MCKEE, VOORHEES & SEASE, P.L.C.
ATTN: PIONEER HI-BRED
801 GRAND AVENUE, SUITE 3200
DES MOINES, IA 50309-2721

EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
----------	--------------

1638

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/766,502	Applicant(s) LAFOUASSE, MARYSE	
	Examiner David H. Kruse	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Rule 105 Request Attachment</u> . |

STATUS OF THE APPLICATION

Continued Examination Under 37 CFR § 1.114

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 21 October 2005 has been entered.
2. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments to the claims.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Request for Information under 37 CFR 1.105

4. Applicant and the assignee of this application are required under 37 CFR § 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application. See ATTACHMENT.
5. This request is being made for the following reasons:

Applicant is claiming a seed comprising at least one set of the chromosomes of maize inbred line PH0GC (claim 1), Applicant is claiming a maize plant having all of the physiological and morphological characteristics of inbred maize line PH0GC (claim 11), and the instant specification is silent about what starting materials and methods were used to produce inbred maize line PH0GC. The instant specification is also silent as to

Art Unit: 1638

the characterization of the chromosomes of maize inbred line PH0GC, and it is unclear what all of the physiological and morphological characteristics of this inbred line are.

The requested information is required to make a meaningful and complete search of the prior art.

Claim Rejections - 35 USC § 112

6. Claims 11-30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is indefinite because it is unclear what the metes and bounds of a maize plant having all of the physiological and morphological characteristics of inbred line PH0GC are. It is unclear if the instant claim only encompasses inbred line PH0GC or if it encompasses broader subject matter.

Claim 25 is indefinite because it is directed to a maize plant derived from inbred line PH0GC, but is dependent upon claim 11 that is not specifically directed to inbred line PH0GC, only a maize plant having all of the physiological and morphological characteristics of inbred line PH0GC. Hence, the metes and bounds of the claim are unclear.

Claims 28 and 29 are indefinite because it is unclear what the metes and bounds of employing the maize plant of claim 11 are. At claim 29, the limitations "restriction fragment length polymorphism enhanced selection", "genetic marker enhanced selection" and "transformation" are not specifically breeding techniques, but ancillary methods that could be used.

Claim 30 is indefinite because the method requires "obtaining an F1 hybrid seed from which maize inbred line PH0GC is a parent", but said claim is dependent upon claim 11 which is directed to "a maize plant having all of the physiological and morphological characteristics of inbred line PH0GC". Hence, it is unclear what the metes and bounds of the claim are, and said limitation does not appear to have proper antecedent basis in claim 11.

Those claims not specifically addressed in this rejection are deemed indefinite because they are dependent upon the invention of claim 11.

7. Claims 1-10 remain rejected and claims 11-30 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 21 July. Applicant's arguments filed 21 October 2005 have been fully considered but they are not persuasive.

Applicant argues that the written description requirement has been satisfied by the actual reduction to practice of F1 hybrid seed/plant produced by inbred maize line PH0GC, by the deposit of a common identifying structural feature of the claimed F1 hybrid seed and plants and by the morphological description of Table 1 of the specification (page 8, 2nd paragraph of the Remarks). These arguments are not found to be persuasive because Applicant only describes a single species of a widely variant

Art Unit: 1638

genus of F1 progeny plants. While a description of a representative number of species is adequate to represent an entire genus, wherein there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus (see MPEP 2163). The art teaches that there are a variety of traits in inbreds that impact hybrid performance, such as yield potential in hybrid combination; dry down; maturity; grain moisture at harvest; greensnap; resistance to root lodging; resistance to stalk lodging; grain quality; disease and insect resistance; ear and plant height; and performance in different soil types, and that these trait are governed by complex genetic systems that make selection and breeding of an inbred line extremely difficult (Carlone, U.S. Patent 5,763,755, paragraph spanning columns 1-2, previously cited). Given the above facts know in the art at the time of Applicant's invention, the claimed genus of F1 progeny plants produced using inbred maize line PH0GC would have substantial variation.

Applicant argues that one of ordinary skill in the art would know that the pericarp tissue of inbred PH0GC is genetically identical to the maternal parent and that intact cells from inbred PH0GC will be a component of the F1 hybrid seed produced with PH0GC as the maternal parent thus the genetic composition of the pericarp tissue of the F1 hybrid seed is an identifying structural feature present in the plants produced from the deposited seed of PH0GC and can be characterized by molecular markers (page 8, 3rd paragraph of the Remarks). This argument is not found to be persuasive because the pericarp tissue of inbred PH0GC only would describe a partial structure and would not describe additional structural or functional features of the claimed F1

Art Unit: 1638

hybrid seed as addressed in the previous Office action on pages 6-7 in view of *In re Wallach* 2004.

Applicant argues that the Applicant "must convey with reasonable clarity to those skilled in the art, as of the filing date sought, he or she was in possession of the invention". Applicant argues that the claims are described where they set forth and define "structural features commonly possessed by members of the genus that distinguish them from others" (page 8, 4th paragraph of the Remarks). This argument is not found to be fully persuasive for the reasons given supra, and the fact that Applicant only describes a single species of a widely variant genus of F1 progeny plants.

Applicant argues that Applicant "are not required to disclose every species encompassed by their claims even in an unpredictable art", and that the specification need only teach one skilled in the art how to make and use the claimed invention (page 9, 2nd paragraph of the Remarks). This argument is not found to be persuasive for the reasons give supra.

Applicant argues that the written description requirement may be satisfied by disclosing functional characteristics where there is a correlation between structure and function, Applicant argues that the disclosure provides sufficiently detailed, relevant identifying characteristics in the Tables provided and therefore has in fact complied with the requirement of written description (page 10, 1st paragraph of the Remarks). This argument is not found to be persuasive because the instant disclosure only provides and adequate written description for inbred maize line PH0GC, because the functional characteristics of an F1 progeny would be correlated as much with the second parent as

Art Unit: 1638

with inbred maize line PH0GC, and the fact that the claimed genus of F1 progeny would widely variant the description in the instant application are deemed insufficient for the claimed subject matter of the instant claims.

Applicant argues that the primary utility of an inbred is in the hybrid it will produce, and Applicant has provided ample description of the hybrids produced by PH0GC in the application as filed (page 10, 2nd paragraph of the Remarks). This argument is not found to be persuasive for the Reasons give supra, in addition the Examiner is not rejecting the claims as lacking utility. The Examiner has already addressed the guidance at MPEP 2163 above. The Examiner will not address Applicant's arguments regarding *Ex part Garing* because that decision by the Board of Appeals is at this point in time is non-precedential.

Applicant argues that the genus of F1 hybrids encompassed by Applicant's claims 1-10 and new claims 11-30 are described with precise definition in a manner which provides structure sufficient to distinguish an F1 hybrid made with Ph0GC from an F1 hybrid not made with PH0GC (page 10, 3rd paragraph of the Remarks). This argument is not found to be persuasive for the reasons given supra.

As the instant rejection is not directed 35 USC 112, second paragraph, Applicant's arguments concerning *Ex part Tanksley* do not appear particularly relevant to the issue of written description.

New claims 11-30 are included in this rejection because it is unclear what is encompassed by a maize plant having all of the physiological and morphological characteristics of inbred line PH0GC as addressed above under 35 USC 112, second

Art Unit: 1638

paragraph. Applicant does not describe all of the physiological and morphological characteristics of inbred line PH0GC, hence it is unclear that Applicant has described the invention at claim 11 as broadly claimed. See *Vas-Cath Inc. v. Mahurkar* 1991 (CA FC) 19 USPQ2d 1111, 1115, which teaches that the purpose of the written description is for the purpose of warning an innocent purchaser, or other person using a machine, of his infringement of the patent; and at the same time, of taking from the inventor the means of practicing upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification.

8. Claims 1-10 remain rejected and new claims 11-30 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for inbred maize line PH0GC, deposited under ATCC Accession No. PTA-4523 and methods of using, does not reasonably provide enablement for a seed comprising at least one set of chromosomes of maize inbred line PH0GC as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 21 July. Applicant's arguments filed 21 October 2005 have been fully considered but they are not persuasive.

Applicant argues that inbred maize lines are primarily used to produce F1 hybrid seed and plants, and that the claimed F1 hybrid seed is routinely and easily produced by crossing a plant from inbred maize line PH0GC with a plant from another inbred maize

Art Unit: 1638

line (page 12, 1st paragraph of the Remarks). This argument is not found to be persuasive. The requirements for enablement under 35 USC 112, first paragraph, are that Applicant must teach how to make and use the claimed invention within the scope of the claimed invention. The art teaches that there are a variety of traits in inbreds that impact hybrid performance, such as yield potential in hybrid combination; dry down; maturity; grain moisture at harvest; greensnap; resistance to root lodging; resistance to stalk lodging; grain quality; disease and insect resistance; ear and plant height; and performance in different soil types, and that these trait are governed by complex genetic systems that make selection and breeding of an inbred line extremely difficult (Carlone, U.S. Patent 5,763,755, paragraph spanning columns 1-2, previously cited). See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) which teaches "That paragraph (35 USC 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved."

Applicant argues that an F1 hybrid as claimed is not a genetically mixed population, but rather is a highly homogenous and reproducible because it is made from the highly homogenous and reproducible inbred maize line PH0GC (page 12, 2nd

Art Unit: 1638

paragraph of the Remarks). This argument is not found to be persuasive as it is directed to F1 hybrids as broadly claimed for the reasons given supra.

Applicant argues that one skilled in the art of corn breeding would know that the F1 plants and seed of claims 1-10 can routinely and easily be produced by crossing PH0GC with another inbred maize line (page 12, 3rd paragraph of the Remarks). This argument is not found to be persuasive because the Examiner is not arguing that a method of using inbred maize line PH0GC is not enabled to make F1 plant, the Examiner is arguing that Applicant has not taught one of skill in the art at the time of the invention how to use the genus of F1 progeny as broadly claimed because of the complex relationship that arises when crossing two inbreds that give rise to unpredictable progeny characteristics, many of which would not be useful as understood by one of skill in the instant art. Given the limited guidance by Applicant the instant claims would have required undue trial and error experimentation of make usefully F1 progeny maize plant as broadly claimed.

The issue of indefiniteness of claims 11-30 is addressed supra. The instant specification states "A breeder of ordinary skill in the art would also be unable to recreate the same line twice from the very same original parents as the breeder is unable to direct how the genomes combine or how they will interact with the environmental conditions." (page 7, lines 8-11 of the specification). This fact is also taught by Kevern (US Patent 5,850,009) at column 4, lines 60-64. The metes and bounds of claim 11 are found to be unclear, and because the claim appears to

Art Unit: 1638

encompass reproducing inbred maize line PH0GC claims 11-30 do not appear to be adequately enabled given the nature of the invention and the skill of one in the art.

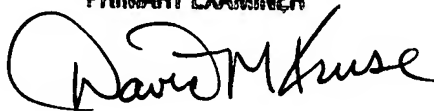
Conclusion

9. No claims are allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The fax telephone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink that reads "David H. Kruse". The signature is written in a cursive style with a large, looped "D" and a stylized "K".

David H. Kruse, Ph.D.
4 January 2006

Art Unit: 1638

11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

ATTACHMENT

Request for Information under 37 CFR 1.105

12. Applicant and the assignee of this application are required under 37 CFR § 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

13. This request is being made for the following reasons:

Applicant is claiming a seed comprising at least one set of the chromosomes of maize inbred line PH0GC (claim 1), Applicant is claiming a maize plant having all of the physiological and morphological characteristics of inbred maize line PH0GC (claim 11), and the instant specification is silent about what starting materials and methods were used to produce inbred maize line PH0GC. The instant specification is also silent as to the characterization of the chromosomes of maize inbred line PH0GC, and it is unclear what all of the physiological and morphological characteristics of this inbred line are. The requested information is required to make a meaningful and complete search of the prior art.

14. In response to this requirement, please provide answers to each of the following interrogatories eliciting factual information:

(i) What were the original parental maize lines used to produce maize inbred line PH0GC?

(ii) What method and method steps were used to produce maize inbred line PH0GC?

Art Unit: 1638

(iii) Have any of said parental maize lines or progeny therefrom been previously publicly disclosed or sold? If so, under what designation were said parental maize lines or progeny disclosed or sold?

(iv) Were any other maize lines produced by said method using said original parental maize lines, and if so, have said produced maize lines been publicly disclosed, sold or disclosed in a U.S. Patent application? If so, under what designation were said other maize lines disclosed or sold?

15. If Applicant views any or all of the above requested information as a Trade Secret, then Applicant should follow the guidance of MPEP § 724.02 when submitting the requested information.

16. The fee and certification requirements of 37 CFR § 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR § 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR § 1.105 are subject to the fee and certification requirements of 37 CFR § 1.97.

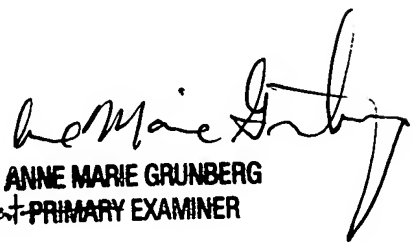
17. The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR § 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is

Art Unit: 1638

unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

18. This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement.

The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.


ANNE MARIE GRUNBERG
Supervisory Patent Examiner